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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/359,260	07/22/99	CAMPBELL	R P3250

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HM12/0912

EXAMINER

RICIGLIANO, J

ART UNIT	PAPER NUMBER
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1627

DATE MAILED:

09/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/359,260**

Applicant(s)  
**Campbell et al**

Examiner  
**Joseph W. Ricigliano**

Group Art Unit  
**1627**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-126 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-126 are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1600 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### *Election/Restriction*

1. This application contains claims directed to patentably distinct species of the claimed invention.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, 18-30, drawn to a method of identifying a culture medium component, classified in in class 435, subclasses 4+, 243+and in class 702, subclass 27 and class 435, digest 51.
- II. Claims 31-35, drawn to a method of defining a test compound library, classified in class 702, subclass 19 and digest 51.
- III. Claims 36-40, drawn to libraries of virtual molecules, classified in class 702 , subclasses 19, 27.
- IV. Claims 41-54 and 57-58, drawn to a method of identifying a culture media component classified in class 435, subclasses 4+, 243+and in class 702, subclass 27 and class 435, digest 51.
- V. Claims 16-17 and 55-56, 113-118 drawn to culture media and culture media components, classified in class 435, subclass 243+ and throughout the 520-570 class series depending on the specific components claimed.
- VI. Claims 59-73, drawn to a method of predicting an indica property of a peptide,

classified in class 702, subclass 19.

VII. Claims 74-95, drawn to methods of identifying peptides with a predicted indication of activity, classified in class 435, subclass 4+ and class 702, subclass 19.

VIII. Claims 96-112 and claim 127, drawn to a method of identifying a culture media component, classified in class 435, subclasses 4+, 243+ and in class 702, subclass 27 and class 435, digest 51.

IX. Claims 119-122 and claims 123-126 drawn to an apparatus for identifying a culture media component (which has been interpreted as a programmed computer recited in means plus function language), and computer program, classified in class 702, subclass 19 and class 435, digest 51.

The inventions are distinct, each from the other because of the following reasons:

Groups I, IV and VIII are drawn to distinct methods. The methods are distinct as they each required different steps. For example: the method of group IV requires defining a first test library not required by the other two methods and the method of group VIII requires the culturing of a first and second groups of cell not required by the other groups of molecules.

The inventions of groups I, IV and VIII and the inventions of group II are drawn to distinct methods. The methods are distinct as they have different steps and produce different results, i.e., defined culture media components and a test compound library.

The inventions of claims I, IV and VIII and the invention of group III are related as distinct methods and a product. In the instant case the methods do not produce the product, it is produced by the method of group II.

Inventions V and inventions I, VI, VIII are related as product and process of use. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the components of group V can be used in materially different processes such as in the preparation of vitamins or dietary supplements of animals.

Invention I, IV and VIII and inventions VI and VII are related as distinct methods. The methods are distinct as the methods of group VI, and VII are directed to predicting the property of a peptide not within a group of test peptides, whereas the methods of groups I, IV and VIII are directed to methods of identifying cell culture media components. Moreover, the method groups I, IV and VIII do not require the methods of groups VI, VII. For example, the methods of groups VI and VII can be practiced with test compounds predicted based upon relationships using less than whole molecule parameters (e.g. a partial smile string, a partial COMFA field etc.).

Inventions I, IV and VIII and invention IX are related as processes and a programmed computer apparatus/ computer program for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by hand.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the

product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by constructing a combinatorial library of compounds, screening it and determining which of the compounds present in the library has the optimal activity of a specific indication and using it as the lead compound. Alternatively, a compound from a assembled group of isomers can be randomly selected.

Inventions II and V are related as process of making a test library and product culture media component made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process makes a different product which is a test compound library.

Invention II and inventions VI and VII are related as distinct processes. The processes are distinct as they use different steps and produce different outcomes. For example, the method of group II selects a library based upon a relationship of compounds with isomers of that compound to select a subset of compounds where as the method of group IV is directed to predicting an indica property of peptides based upon at least one whole molecule parameter and measurements thereof and group VII is directed to a method of identifying a peptide using a first and second peptide libraries.

Inventions II, VI and VIII and invention IX are related as processes and a programmed computer apparatus/ computer program for the apparatus. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this

case the processes can be practiced by hand.

Inventions III and V are related as distinct products; a library of molecules and a culture media component. The inventions are distinct as the libraries comprise different components than the single media components. Moreover, the libraries can be used in alternative methods of screening such as in receptor binding analysis and hence the products are capable of independent operation.

Inventions VI and VII and inventions III and V are related as processes of making and a product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group III can be made by constructing a combinatorial library of compounds, screening the library and determining which of the compounds present in the library have the activity. The active compounds can be assembled into a library as required by group III and the optimally active compound can be used as a lead compound or a culture media component as required by group V. These methods are materially different than the methods of groups VI and VIII as they require different steps.

Inventions III and V and the invention of group XI are related as product libraries and media components and a programmed computer apparatus/computer program for the apparatus. In this case the products of group III and V can be made without the computer or program of group IX. Moreover, the products can be operated without the invention of group IX for example in screening, testing, culturing, radio-tracer incorporation and growth supplement formation processes.

The inventions of groups VI and VII are related as distinct processes. The process of group VI predicts an indication of a property of a peptide and the method of the group VII identifies a peptide with a predicted indication. Thus, the processes produce different results. Moreover, the processes require different steps such as the step of identifying a second peptide library as in group VII.

2. Because these inventions are distinct for the reasons given above and the search required for Groups I-IX are not coextensive, restriction for examination purposes as indicated is proper.

This application contains claims directed to patentably distinct species of the claimed invention.

3. If applicants elect the invention of group I applicants are required to elect from the following species of the claimed invention:

A.) Functions for performing the method, (e.g.  $f(x)$ ) setting forth all variables. Applicants should also indicate if the function is of the form  $d(x_1, x_2)$  as in claim 10 for example.

B) Parameters. Applicants should set forth a parameter used in the analysis, for example from those set forth in claims 15. Note that, the parameters set forth in claims 13-14 are generic to a plurality of species and election of one of these will be considered as nonresponsive.

C) Test libraries. Applicants should elect a test library for examination on the merits for example from those set forth in claim 18.

D) Applicants should indicate if the process is to include or exclude the step of forming a plurality of cell cultures as required by claim 23. If the process is to include this step then applicants should further elect a specific measured property. Note that the election must



be specific, for example, election of altered production of steroids, carbohydrates or antibiotics etc. will not be considered responsive unless the specific compound is recited (e.g., estrogen etc.). Moreover, if the elected property is to be altered peptide or protein production then an explicit recitation of the protein or peptide must be stated. The members set forth in claims 28-29 are generic to innumerable species an election of one of these will be considered non-responsive unless accompanied by a statement of the specific member (e.g., enzymes are not specific, trypsin is a specific enzyme).

A proper election of species requires a selection from each subgenus A-D.

Currently, claim 1 is generic and will be examined with any of the species elected.

4. If applicants elects the invention of group II applicants are required to elect from the following species of the claimed invention:

A) Test libraries. Applicants should elect a test library for examination on the merits, for example from those set forth in claim 34.

B) Space-filling. Applicants should indicate if the elected species is required to include or exclude the use of space-filling techniques as in claim 32.

A proper election of species requires a selection from each subgenus A-B.

Currently, claims 31 is generic and will be examined with any of the species elected.

5. If applicants elects the invention of group III applicants are required to elect from the following species of the claimed invention:

A) Test libraries. Applicants should elect a test library for examination on the merits, for example from those set forth in claim 34( which is not part of this group but is used for exemplification purposes).

Currently, claims 31 is generic and will be examined with any of the species elected.

6. If applicants elects the invention of group IV applicants are required to elect from the following species of the claimed invention:

A ) Functions for performing the method, (e.g.  $f(x)$ ) setting forth all variables. Applicants should also indicate if the function is of the form  $d(x_1, x_2)$  as in claim 50 for example.

B) Parameters. Applicants should set forth a specific parameter used in the analysis. Note that, the those set forth in claims 51-52 are generic to a plurality of species and election of one of these will be considered as nonresponsive. A specific election would for example be a specific whole molecule parameter such as charge or molecular weight.

C) Compound space. Applicants should elect a compound space for examination on the merits for example from those set forth in claim 53.

A proper election of species requires a selection from each subgenus A-C.

Currently, claim 41 is generic and will be examined with any of the species elected.

7. If applicants elects the invention of group V applicants are required to elect a specific culture medium component for examination on the merits. In order to avoid confusion and to proceed with more compact prosecution applicants should set forth the election by structure.

8. If applicants elects the invention of group VI applicants are required to elect from the following species of the claimed invention:

A ) Applicants should specify the number and type of whole molecule parameters used for example from those set forth in claims 62 and 64.

B) Applicants should set forth a specific activity of the test peptides for examination on the merits. Note that generic election of a biological activity or inducement or activation

of receptor etc. will not be considered specific as they are generic to a plurality of species. A specific election needs to set forth a specific activity (e.g., Induction of Beta lactamase, induction of Beta receptor expression, etc.).

A proper election of species requires a selection from each subgenus A-B.

Currently, claim 59 is generic and will be examined with any of the species elected.

9. If applicants elects the invention of group VII applicants are required to elect from the following species of the claimed invention:

A ) Functions for performing the method, (e.g.  $f(x)$ ) setting forth all variables. Applicants should also indicate if the function  $d(x_1, x_2)$  is employed as in claim 80 for example.

B) Parameters. Applicants should indicate the number and type of whole molecule parameters and set forth the parameters used in the process, for example from those set forth in claims 83-86.

C) Applicants should set forth a specific activity of the test peptides for examination on the merits. Note that generic election of a biological activity or inducement or activation of receptor etc. will not be considered specific as they are generic to a plurality of species. A specific election needs to set forth a specific activity (e.g., Induction of Beta lactamase, induction of Beta receptor expression, etc.).

A proper election of species requires a selection from each subgenus A-C.

Currently, claim 74 is generic and will be examined with any of the species elected.

10. If applicants elects the invention of group VIII applicants are required to elect from the following species of the claimed invention:

A ) Define and undefined media. Applicants should indicate if the first and second media used are defined or undefined media.

B) Omission of components. Applicants should indicate if the elected species is to include or exclude the omission of media components. (see claims 97-99 for example).

C) Undefined protein components. Applicants should indicate the process employs undefined protein components. If they are employed, applicants should select a specific component and the concentration range employed. ( see claims 102-140 for example).

Note that election of members from claim 102 will be considered nonresponsive unless accompanied by a specific election. (For example, election of extracts is not specific whereas yeast extract is a specific election).

D) Property measured. Applicants should elect a specific measured property for example from those set forth in claims 108-112. Note that the election must be specific, for example, election of altered production of steroids, carbohydrates or antibiotics will not be considered responsive unless the specific compound is recited (e.g., estrogen etc.).

Moreover, if the elected property is to be altered peptide or protein production then an explicit recitation of the protein or peptide must be stated (e.g., enzymes are not specific, trypsin is a specific enzyme).

A proper election of species requires a selection from each subgenus A-D.

Currently, claim 96 is generic and will be examined with any of the species elected.

11. If applicants elect the invention of group IX applicants are required to elect a specific function, (e.g.  $f(x)$ ), setting forth all variables. Applicants should also indicate if the function is of the form  $d(x_1, x_2)$  as in claims 122 and 126 for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Donna Fugit on 8/30/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention,

the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Ricigliano Ph. D. whose telephone number is (703) 308-9346. The examiner can be reached on Monday through Thursday from 7:00 A.M. to 5:30 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439.

Joseph W. Ricigliano Ph. D.

August 30, 2000

  
DR. JYOTHSNA VENKAT PH.D.  
SUPERVISORY PATENT EXAMINER  
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